UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,917	10/11/2005	John Bernard March	9013-56IP	8053

20792 7590 10/06/2009

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
SNYDER, STUART	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
10/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,917	MARCH ET AL.	
	Examiner	Art Unit	
	STUART W. SNYDER	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 April 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/1/2005 & 9/1/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of HBV as target of vaccine and HBsAg/HBeAg and INFα/β as expressed heterologous proteins in the reply filed on 5/18/2009 is acknowledged. The traversal is on the ground(s) that a search for other hepatitis viruses and their antigens would be coextensive with a search for HBV.

   This is not found persuasive because it is well know in the art of viral immunology that successful vaccines are unique to the type of nature of the virus. In the instant case, the phrase "hepatitis virus" encompasses viruses of several different viral groups, families and genuses: HAV is a Hepatoviridae in the Picornavirus Family and a Group IV ((+)ssRNA) virus; HBV is a Hepadnaviridae in Group VII (dsDNA-RT virus) virus; HCV is a hepecivirus in the family Flaviviridae and a Group IV ((+)ssRNA) virus; HDV is a Deltavirus in Group V ((-)ssRNA) virus; and HEV is in the Hepeviridae family, genus Hepevirus in Group IV ((+)ssRNA) virus. Furthermore, whereas successful vaccines exist for HAV and HBV, no such vaccines exist for the other three viruses. Thus the search parameters would not be coextensive.

   The requirement is still deemed proper and is therefore made FINAL.

2. In a telephonic interview with Alice Bonnan, agreement was reached that the elected species read on claims 1-21.

Drawings

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because of the following: In Figures 2(a)-2(h), it is unclear what the vertical line in each figure represents; In Figure 5, there is no indication of which panel represents rabbits A-F. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

4. Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 21 recites "for use in the prophylaxis and/or treatment of a disease in a human or animal". The Examiner is unaware of any other real world use of vaccine formulations other than prophylaxis and/ or treatment of animal diseases.

Claim Rejections - 35 USC § 112, 1st Para.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for hepatitis A and hepatitis B vaccine

formulations, does not reasonably provide enablement for HCV, HDV or HEV vaccine formulations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. A recent review (Stoller-Keller, et al. Development of hepatitis C virus vaccines: challenges and progress. Expert Rev Vaccines. 2009 Mar; 8(3):333-45) describes the scientific impediment to finding an effective vaccine and includes the considerable variability of this RNA virus and the observation that convalescent humans and chimpanzees could be re-infected after re-exposure. Furthermore, both B-cell and T-cell stimulation may be necessary for successful prophylaxis. Moreover, therapeutic vaccine formulations currently being evaluated in clinical trials are facing the fact that the immune system of chronic carriers is impaired and needs the restoration of T-cell functions to enhance their efficacy. A specific hepatitis D vaccine may not be required because of the well-known dependence on the virus on HBV for replication. In the case of hepatitis E, there is no current cell culture replication methodology and thus live or inactivated vaccines are impossible; in a clinical trial of subunit vaccines (Aggarwal and Jameel, Hepatitis E vaccine. Hepatol Int. 2008 September; 2(3): 308–315), the vaccine seemed to be 95% effective, however the effectiveness was apparently short-lives as 44% of the subjects had anti-HEV antibody titers below the lever considered as protective. Thus, after nearly 20 years of effort in developing vaccines against HCV, HDV and HEV, no effective vaccine has been developed for any of these viruses and the technical

and scientific challenges are such that it is not clear an effective vaccine may be developed.

Claim Rejections - 35 USC § 112, 2nd Para.

6. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim depends on claim 9 which in turn depends on claim 5, which recites, "a bacteriophage particle the surface of which is unmodified". However, claim 17 recites, "wherein the bacteriophage has been modified to express the polypeptide on the surface of the phage particle". It is unclear to the Examiner how the surface of a phage particle could be devoid of modification while simultaneously display an exogenous polypeptide.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 17 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7128916. Although the conflicting claims are not identical, they are not patentably distinct from each other because each requires an exogenous polypeptide antigen of a virus to be expressed on the surface of a phage and further be comprised of a eukaryotic promoter and an exogenous nucleic acid molecule under control of the eukaryotic promoter and encoding a virus polypeptide.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648

sws